

COVID-19 Vaccine Information Brief

April 18, 2023

IMPORTANT/NEW COVID-19 Vaccine Information

- Coronavirus (COVID-19) Update: FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines
- Removing Monovalent Moderna and Pfizer COVID-19 vaccine from IRIS and Physical Inventory
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- Preventing Administration of Expired Vaccines and Wastage Guidance
- COVID-19 Prep Act Declaration
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CORONAVIRUS (COVID-19) UPDATE: FDA AUTHORIZES CHANGES TO SIMPLIFY USE OF BIVALENT mRNA COVID-19 VACCINES

Effective immediately, April 18, 2023, the U.S. Food and Drug Administration (FDA) amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines to simplify the vaccination schedule for most individuals. The full new release is available on the FDA [webpage](#).

- **This action includes authorizing the current bivalent vaccines (original and omicron BA.4/BA.5 strains) to be used for all doses administered to individuals 6 months of age and older, including for an additional dose or doses for certain populations.**
- **The monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.**

The Advisory Committee on Immunization Practices (ACIP) is meeting, Wednesday, April 19, 2023, to discuss recommendations for COVID-19 vaccines. Following the ACIP meeting, CDC will issue official recommendations and update the Interim Clinical Considerations (ICC).

What You Need to Know:

- **Most individuals, depending on age, previously vaccinated with a monovalent COVID-19 vaccine** who have not yet received a dose of a bivalent vaccine may receive a single dose of a bivalent vaccine.
- **Most individuals who have already received a single dose of the bivalent vaccine** are not currently eligible for another dose. The FDA intends to make decisions about future vaccination after receiving recommendations on the fall strain composition at an FDA advisory committee in June.
- **Individuals 65 years of age and older who have received a single dose of a bivalent vaccine** may receive one additional dose at least four months following their initial bivalent dose.
- **Most individuals with certain kinds of immunocompromise who have received a bivalent COVID-19 vaccine** may receive a single additional dose of a bivalent COVID-19 vaccine at least 2 months following a dose of a bivalent COVID-19 vaccine, and additional doses may be administered at the discretion of, and at intervals determined by, their healthcare provider. However, for immunocompromised individuals 6 months through 4 years of age, eligibility for additional doses will depend on the vaccine previously received.
- **Most unvaccinated individuals** may receive a single dose of a bivalent vaccine, rather than multiple doses of the original monovalent mRNA vaccines.
- **Children 6 months through 5 years of age who are unvaccinated** may receive a two-dose series of the Moderna bivalent vaccine (6 months through 5 years of age) OR a three-dose series of the Pfizer-BioNTech bivalent vaccine (6 months through 4 years of age). Children who are 5 years of age may receive two doses of the Moderna bivalent vaccine or a single dose of the Pfizer-BioNTech bivalent vaccine.
- **Children 6 months through 5 years of age who have received one, two or three doses of a monovalent COVID-19 vaccine** may receive a bivalent vaccine, but the number of doses that they receive will depend on the vaccine and their vaccination history.

Related COVID-19 Vaccine Information

- [Pfizer-BioNTech COVID-19 Vaccines](#)
 - [Moderna COVID-19 Vaccines](#)
 - [COVID-19 Vaccines](#)
 - [Emergency Use Authorization for Vaccines Explained](#)
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REMOVING MONOVALENT MODERNA AND PFIZER COVID-19 VACCINE FROM IRIS AND PHYSICAL INVENTORY

Effective immediately, April 18, 2023, all Moderna and Pfizer MONOVALENT mRNA COVID-19 vaccines should not be administered and should be removed from IRIS and physical inventory. These vaccines should be removed from IRIS using the reason code “Open vial but all doses not administered”. Healthcare providers can use the [Adjusting COVID-19 Vaccine Inventory for Wastage](#) instructions to account for wasted doses. IRIS staff are available to help manage IRIS inventory by calling 800-374-3958.

Moderna and Pfizer MONOVALENT mRNA COVID-19 vaccines should be disposed of at the provider level. The federal government does not have a method to return wasted or expired COVID-19 vaccines.

PREVENTING ADMINISTRATION OF EXPIRED VACCINES AND WASTAGE GUIDANCE

Administering expired vaccines continues to be a reported vaccine administration error. However, this error can be prevented by following these suggestions:

- Providers should check the expiration dates of all vaccines weekly. Check vaccine expiration dates using the manufacturers’ online expiry checking tools:
 - [Moderna Vial Expiration Checker](#)
 - [Pfizer-BioNTech COVID-19 Vaccine Expiry Checker](#)
 - [Novavax Expiry Date Checker](#)
 - [Janssen Expiry Checker](#)
 - Remove expired vaccine from storage units and discard according to state and local regulations.
 - Check the expiration date prior to preparing or administering the vaccine. NEVER administer expired vaccine.
 - If expired vaccine is inadvertently administered:
 - Review guidance on the CDC website: [Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates | CDC](#).
 - Report vaccine administration errors to the [Vaccine Adverse Event Reporting System](#).
 - For persons seeking vaccine who have not completed a primary series, see [Clinical Guidance for COVID-19 Vaccination | CDC](#).
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COVID-19 PREP ACT DECLARATION

HHS released a [fact sheet](#) about an upcoming amendment to the COVID-19 PREP Act declaration. This will be the eleventh amendment to the declaration and seeks to clarify issues around provider liability protections. All COVID-19 vaccines and treatments **for which distribution is currently directed by the United States Government (USG)** are covered by PREP Act protections and flexibilities.

Even once vaccines, tests, and treatments move away from being distributed under a USG agreement as a transition to traditional pathways for procurement, distribution, and payment, PREP Act coverage will not automatically terminate in all instances. Rather, the duration of PREP Act coverage for COVID-19 countermeasures will be determined by the terms of the PREP Act declaration in place at the time.

Key changes that Secretary Becerra plans to make under the upcoming amended declaration include:

Key changes under the upcoming amended declaration include:

- **Extending coverage for COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests.** PREP Act immunity from liability will be extended through December 2024 to pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 and seasonal influenza vaccines (to those individuals three and over, consistent with other requirements), and COVID-19 tests, regardless of any USG agreement or emergency declaration.
- **Extending coverage through December 2024 for Federal agreements.** This includes all activities related to the provision of COVID-19 countermeasures that are 1) provided based on a Federal agreement (including the vaccines and treatments purchased and provided by the USG), or 2) directly conducted by the USG, including by Federal employees, contractors or volunteers.
- **Ending of coverage for certain activities.** Once products are no longer distributed under a USG agreement, PREP Act coverage will no longer extend to the following activities: COVID-19 vaccination by non-traditional providers (e.g., recently retired providers and students); and COVID-19 vaccinations across state lines by licensed providers and pharmacists and pharmacy interns.
- **Ending of coverage for routine childhood vaccinations.** Once there is no emergency in effect, PREP Act coverage will no longer extend to all routine childhood vaccinations by pharmacists, pharmacy interns, and pharmacy technicians.

Some of the key features that will not change under the amended declaration include:

- **No immediate impact on USG distributed COVID-19 countermeasures.** As noted above, the amended PREP Act declaration will not have any immediate impact on COVID-19 vaccines, treatments, and tests currently distributed by the USG—either now or when the COVID-19 PHE ends on May 11.
 - **No change to coverage for certain prescribing and dispensing of COVID-19 oral antivirals.** The PREP Act will continue to offer liability immunity for pharmacists, pharmacy technicians, and pharmacy interns dispensing COVID-19 treatments, in accordance with a U.S. Food and Drug Administration (FDA) authorization, such as the oral antiviral treatments Paxlovid and Lagevrio. In the case of Paxlovid, pharmacists are permitted to prescribe the treatment under certain circumstances. These oral antiviral treatments are available at over 40,000 provider locations, including over 35,000 retail pharmacies.
 - **No change to the “Test to Treat” program.** Pharmacists and other providers prescribing tests in the “Test to Treat” program will continue to receive liability protection under the PREP Act.
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ANCILLARY SUPPLY KIT UPDATES

Check expiration dates before using any ancillary kit supplies or other medical equipment.

This includes diluent, when needed.

- Do NOT discard the entire COVID-19 vaccine ancillary kit based on the date printed on the box’s ancillary kit label. The expiration date printed on the box’s ancillary kit label does NOT apply to supplies with an expiration date printed on each item’s packaging.
 - Note that expiration dates for masks and face shields are displayed on the ancillary supply kit label.
 - The expiration dates for other supplies (needles, syringes, alcohol prep pads, etc.) are printed on the individual packaging of each item.
 - Promptly discard any expired items according to state and local regulations.
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COVID-19 VACCINE INFORMATION BRIEFS

COVID-19 Vaccine Information Briefs will continue to be issued after the expiration of the Public Health Emergency on May 11, 2023. As additional information is received regarding the PREP Act and commercialization of COVID-19 vaccines, Information Briefs will be shared with healthcare providers.